AMENDMENTS TO THE DRAWINGS:

Please replace Figure 1 and Figures 1(i)-1(vi) with the attached substitute Figures 1A-1G.

REMARKS

In the Official Action dated July 25, 2006, Applicants' submission filed on May 10, 2006 has been entered. Claims 1, 2, 7-10, 25, 28-30 and 36-52 are pending and under consideration on the merits. Figure 1 and claims 37, 39-40 and 43 are objected to for certain informalities. Claims 1, 2, 7-10, 25, 28-30, 36-44 and 47-52 are rejected as allegedly lacking enabling support. Claims 1, 2, 7-10, 25, 28-30, 36-44 and 47-52 are rejected as allegedly failing to comply with the written description requirement. Claims 38-44 and 48-51 are also rejected as allegedly containing new matter. Claims 1, 2, 7, 9, 10, 25, 28-30, 36, 37, 43, 44, 46-52 are rejected as allegedly indefinite.

This response addresses each of the Examiner's objections and rejections. Accordingly, the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

The disclosure is objected to for certain informalities. The Examiner indicates that all of the parts of Figure 1 are not identified clearly in the Brief Description of the Figures. Applicants submit together with this response replacement drawings that are labeled Figure 1A through 1G, as suggested by the Examiner. As such, the objection is obviated and withdrawal thereof is respectfully requested.

Claims 37, 39, 40 and 43 are objected to for certain informalities. Specifically, the Examiner states that Claim 37 appears to be missing the word "in" by reciting "the nucleotide sequence as set forth SEQ ID NO: 3." The Examiner indicates that the word "extracellular" is spelled inconsistently in Claims 38-40. Both of Claims 39 and 40 depend from Claim 38. The Examiner requires that the recitations of "extra-cellular" and "extra cellular" in Claims 39 and 40, respectively, be corrected to "extracellular" to be inconsistent with Claim 38. The Examiner

further indicates that the first letter of the word "claim" in claim 43 is capitalized. The Examiner requires that this letter be corrected in lowercase as in the other claims.

In response, Applicants have amended Claims 37, 39-40 and 43 in accordance with the Examiner's requirements. As such, the objection is obviated and withdrawal thereof is respectfully requested.

Claims 1, 2, 7-10, 25, 28-30, 36-44 and 47-52 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enabling support. The Examiner acknowledges that the specification enables an isolated nucleic acid molecule encoding a polypeptide comprising the entire extracellular domain (ECD) of the NR4 receptor (SEQ ID NO: 4). However, the Examiner alleges that the specification does not provide enablement for an isolated nucleic acid molecule encoding a derivative of SEQ ID NO: 4 that does not comprise the entire ECD. The Examiner states that the claims that recite nucleic acids comprising "a nucleotide sequence as set forth in SEQ ID NO: 3" have been broadly interpreted to encompass any shorter nucleotide sequences that are found within the longer sequence of SEQ ID NO:3. Similarly, claims that recite nucleic acids comprising a sequence encoding "an amino acid sequence as set forth in SEQ ID NO:4" have been broadly interpreted by the Examiner to encompass any nucleic acid comprising any shorter nucleotide sequence that encodes a fragment of SEQ ID NO: 4. The Examiner alleges that Applicants have provided little or no guidance beyond the mere presentation of sequence data to enable one skilled in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change.

Applicants observe that the claimed derivatives of SEQ ID NO: 4 include functional derivatives, which can bind with IL-13, and non-functional derivatives, which are immunologically interactive with antibodies to the NR4 receptor, or antibodies to functional

derivatives of NR4. It is respectfully submitted that both functional derivatives and non-functional derivatives are important to Applicants. Applicants observe that the Examiner appears to be concerned that the claims as written may encompass any SEQ ID NO: 4 variants, e.g., SEQ ID NO: 4 variants that neither bind or interact with IL-13 nor are immunologically interactive with antibodies of NR4. In order to clarify the language in the claim and in an effort to favorably advance prosecution, Applicants amended the claims to recite "wherein the derivative binds with IL-13 or is immunologically interactive with antibodies to the IL-13 receptor alpha chain."

The Examiner also asserts that other than a soluble NR4 receptor variant that consists of the entire ECD, the specification does not provide guidance as to which variants would still retain the activity of binding with IL-13. In addition, the Examiner appears to assert that the non-functional derivatives of NR4 are not useful. The Examiner asserts that the ability to produce antibodies to non-functional derivatives of NR4 does not provide a use for such non-functional derivatives.

Applicants respectfully submit that that the specification, e.g., at page 22, lines 13-15, expressly teaches that NR4 and its derivatives can be used to screen for naturally occurring antibodies to NR4, which antibodies may occur in autoimmune diseases. Accordingly, Applicants submit that the specification enables one skilled in the art to make and use nucleic acid molecules encoding non-functional derivatives of NR4.

With respect to the Examiner's allegation that the present application only teaches derivatives comprising the entire unaltered ECD, Applicants respectfully direct the Examiner's attention to Examples 6 and 11 of the specification, in which several examples of sub-domains of either murine or human ECD have been disclosed. Moreover, Applicants submit that WO 00/18932 demonstrates that one skilled in the art can readily use the information of a nucleic acid

molecule encoding the NR4 receptor to make and use a nucleic acid molecule encoding the "cytokine binding portion" of ECD. A copy of WO 00/18932 was previously submitted as Exhibit A together with the RCE dated May 10, 2006. Applicants submit that according to WO 00/18932, by "cytokine binding portion" is meant "the minimal portion of the extracellular domain necessary to bind the cytokine." See page 14, line 19-20 of WO 00/18932. Applicants submit that WO 00/18932 teaches that fragments smaller than the ECD will function to bind the cytokine. An embodiment of WO 00/18932 is directed to making and using a polypeptide containing a minimal portion of the ECD necessary to bind the cytokines, based on the sequence information of the cytokine receptor with the entire ECD.

Thus, Applicants respectfully submit that based on the disclosure of the present application together with the knowledge well known in the art at the critical time, one skilled in the art can make and use variants of NR4 (or derivatives of SEQ ID NO: 4) that contain less than full-length ECD (or so-called minimal portion of ECD), without undue experimentation.

As such, the rejection of Claims 1, 2, 7-10, 25, 28-30, 36-44 and 47-52 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enabling support is overcome and withdrawal thereof is respectfully requested.

Claims 1, 2, 7-10, 25, 28-30, 36-44 and 47-52 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner alleges that the broadly claimed genus additionally encompasses polynucleotides that may be completely unrelated to the polynucleotide encoding NR4 and its derivatives. The Examiner alleges that the claims are not limited to polypeptides that comprise the extracellular domain of SEQ ID NO: 4 (residues 28-346). The Examiner states that the claims encompass polynucleotides that vary substantially in length and also in nucleotide composition. The

Examiner alleges that the claimed genus additionally encompasses polynucleotides that may be completely unrelated to the polynucleotide SEQ ID Nos:1 and 3.

Applicants respectfully disagree with the Examiner's allegations. Applicants respectfully submit that the present application provides sufficient descriptive support that satisfies the requirement of 35 U.S.C. § 112, first paragraph. Moveover, in view of the above-mentioned amendments to the claims, these claims, as amended, do not encompasses any polynucleotides that are completely unrelated to the polynucleotide SEQ ID Nos:1 and 3 as alleged by the Examiner. Applicants further submit that the arguments above directed to the enablement rejection should also be sufficient to demonstrate that the present inventors possessed the full scope of the invention at the time the present application was filed.

> The "written description" clause of section 112 has been construed to mandate that the specification satisfy two closely related requirements. First, it must describe the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention without undue experimentation .... Second, it must describe the invention sufficiently to convey to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, *i.e.*, that the patentee invented what is claimed .... Those two requirements usually rise and fall together. That is, a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and *vice versa*.

LizardTech, Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 76 USPQ2d 1724, 1731-32 (Fed. Cir. 2005), (Emphasis added)

As such, the rejection of 1, 2, 7-10, 25, 28-30, 36-44 and 47-52 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement is overcome and withdrawal thereof is respectfully requested.

Claims 38-44 and 48-51 are also rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. The Examiner states that Claims 38-42 each encompass a genus of isolated nucleic acids comprising an extracellular domain of an IL-13 haemopoietin receptor. The Examiner states that Claim 38 encompasses a genus of isolated nucleic acids "comprising a sequence of nucleotides that encodes an extracellular domain of an IL-13 haemopoietin receptor." The Examiner alleges that the term "IL-13 haemopoietin receptor" is not defined in the specification. Thus, the Examiner interprets the term broadly to encompass any IL-13 receptor. The Examiner alleges that the language used, i.e., "a sequence of nucleotides that encodes an extracellular domain" indicates that the genus is not limited to any particular portion of an extracellular domain (ECD).

In an effort to favorably advance prosecution, Applicants amended claim 38 to recite "IL-13 receptor alpha chain," which term is clearly described in the specification. Applicants reserve the right to pursue the broader scope of claim 38.

With respect to the Examiner's allegation regarding claims 43-44 and 48-51, Applicants respectfully submit that the specification, e.g., at Examples 6, 11 and 12, together with Figure 7, discloses the specific claimed fragments. The Examiner further alleges that the transition language "consisting essentially of" is broad enough to encompass an unlimited number of changes to the recited fragments, which are not supported by the specification. In an effort to favorably advance prosecution, Applicants have amended these claims by replacing "consisting essentially of" with "consisting of." Applicants reserve the right to pursue these claims in a broader scope.

As such, the rejection of Claims 38-44 and 48-51 under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter is overcome and withdrawal thereof is respectfully requested.

Claims 1, 2, 7, 9, 10, 25, 28-30, 36, 37, 43, 44, 46-52 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. The Examiner alleges that Claim 1 could be interpreted in two different ways. The Examiner alleges that Claim 2 is indefinite because it is unclear whether the isolated nucleic acid is limited to those comprising SEQ ID NO:3 or whether it can comprise variants of SEQ ID NO:3 that encode derivatives of the receptor. The Examiner alleges that Claim 7 is indefinite because it is unclear whether the final part of the claim (reciting, "...a nucleic acid molecule which hybridizes...") is limited by the first part of the claim reciting that the molecule encodes an IL-13 receptor. The Examiner alleges that Claim 37 is indefinite. It is not clear what is encompassed by "the nucleotide sequence as set forth SEQ ID NO:3." The Examiner alleges that Claims 43, 44 and 48-51 are indefinite for certain claim scope inconsistency between independent and dependent claims. The Examiner alleges that Claim 52 is indefinite because it recites "the isolated nucleic acid molecule of claim 38 comprising the amino acid sequence set forth in SEQ ID NO: 4."

Applicants have amended the claims in accordance with the Examiner's suggestions and requirement. Applicants submit that Claims 37-39, as amended, are clear and definite. As such, the rejection of Claims 1, 2, 7, 9, 10, 25, 28-30, 36, 37, 43, 44, 46-52 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite is overcome and withdrawal thereof is respectfully requested.

Claims 45 and 46 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,256,560 to Lawman et al. The Examiner states that Claim 45 encompasses any

isolated host cell that expresses the haemopoietin receptor encoded by SEQ ID NO:3. The Examiner alleges that claim 45 encompasses isolated cells that recombinantly or naturally express this polypeptide. The Examiner states that the instant specification teaches that the polynucleotide of SEQ ID NO:3 was isolated from a human bone marrow cDNA library. The Examiner asserts that isolated human bone marrow cells would inherently express a polypeptide encoded by SEQ ID NO: 3. The Examiner alleges that Lawman teaches preparation of a cDNA library from bone marrow cells. Thus, the Examiner contends that such a preparation would require isolation of the bone marrow cells. Therefore, the Examiner alleges that the bone marrow cells taught by Lawman anticipate instant claim 45. However, the Examiner appears to suggest that this rejection can be overcome by amending claim 45 to recite an isolated host cell that recombinantly expresses the haemopoietin receptor encoded by SEQ ID NO: 3.

In an effort to favorably advance prosecution, Applicants have amended Claim 45 to recite "recombinantly expresses" as suggested by the Examiner. Applicants submit that since Lawman et al. merely teach an isolated host cell that naturally expresses the haemopoietin receptor encoded by SEQ ID NO: 3, Claim 45, as amended, and Claim 46, which depend from Claim 45, are not anticipated by Lawman et al.

As such, the rejection of Claims 45 and 46 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,256,560 to Lawman et al. is overcome and withdrawal thereof is respectfully requested.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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